



**Switch Scene:**

**The US FDA to Become  
“Proactive” on Switches**  
New FDA 2004 Budget Announces  
Switch Policy Changes  
FDA Pressures Switch of More  
Non-Sedating Antihistamines

In a possible seismic change in the role of Rx-to-OTC importance in the US healthcare system, the US FDA has announced and begun to implement a major emphasis on increasing switches as a means of improving public health.

Moreover, SWITCH believes they are executing that policy change by pressuring Pfizer to switch Zyrtec and presumably Aventis to switch Allegra, both non-sedating antihistamines.

There were clear warnings that this could happen following the Citizen’s Petition Meeting of May 11, 2001 regarding the suitability of non-sedating antihistamines for over-the-counter status. (See later for more on this historic meeting.)

Well, apparently, now that we finally have a new FDA commissioner, the threat has been set as policy and the execution of that policy is beginning.

As we have mentioned in our past issues, the switch environment fallout from the non-sedating antihistamines situation could wash over numerous other categories, the most obvious being the proton pump inhibitor market given the impending switch of Prilosec. After these are switched, there are numerous categories that could be considered vulnerable.

Of course, not every category is as obvious as non-sedating antihistamines for switching. However, non-life-threatening indications are likely to be up for review along with the medicines used for treatment.

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What is it that makes the difference between the success of one Rx-to-OTC switch and the failure of another? In fact, while there are no consistently successful Rx-to-OTC switch companies, there are some consistently UNsuccessful companies at switching products to OTC status. Why is that?

What is clear is that the consistent failures were because the company did not enable or allow their internal personnel the full opportunity to pool the total knowledge of the multi-disciplinary switch team and organize that knowledge into units and then into objective scenarios. Instead, one view dominated and that view turned out to be short-sighted.

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